100 INDEPENDENCE MALL WEST PHILADELPHIA, PA 19106-2399 U.S.A TELEPHONE (215) 592-3000 CABLE ADDRESS: ROHMHAAS CENTRAL FAX (215) 592-3377

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February 18, 1997



Document Processing Center (TS-790) Attn: Section 8(e) Coordinator Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency 401 M Street, S.W. Washington, DC 20460

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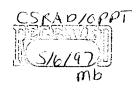
Dear Sir:

Rohm and Haas Company submits this notice in accordance with Section 8(e) of the Toxic Substances Control Act.

A two-generation reproductive toxicity study of [] is in progress. Dietary in this study are 1000, 5000 and 20000 ppm active ingredient. concentrations of [

We have recently completed the lactation phase for the first generation of pups. There were no treatment-related effects on body weights of parental animals, mating or fertility parameters, numbers and survival of offspring, or growth of offspring through day 14 of lactation. However, treatment-related decreases in pup weight and spleen weight (both absolute and relative to body weight) at day 21 of lactation was observed at all dose levels. In the first mating, there was not a clear dose-response in the low and mid-dose groups. Therefore, the parental animals were remated to confirm the effects. The decreased pup weight was confirmed at all doses. Absolute spleen weight was also decreased in the second mating at all doses, but spleen weight relative to body weight was reduced at only the mid and high dose. Therefore, the relationship of the decreased spleen weight to reduced body weight is uncertain. Histopathological examination of the spleens will be performed to determine whether there is a specific target organ effect.

The decreased body weight occurs at a time when the pups are becoming less dependent on nursing, and beginning to consume the test diet directly. It is unclear whether the decreased body weight is due directly to [] toxicity (and increased sensitivity in immature animals) or secondary to decreased feed consumption related to irritation or decreased palatability. Indeed, during the premating phase of the P1 animals in this study, decreased palatability was indicated by a transient



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decrease in feed consumption (16%) in high dose females during the first week of treatment. Further studies are being planned to address this question.

[] is the Rohm and Haas experimental designation for [A diagram of the chemical structure is included in Attachment I.

].

Rohm and Haas has produced only small quantities of this new substance for exploratory testing purposes. Only a very limited number of highly trained laboratory personnel have been involved in the synthesis and testing of the substance. Appropriate safety procedures have been employed to preclude any exposure to new pesticidal candidates whose toxicological properties have not been fully defined. These employees have been advised of the results of these studies.

Because of this very low potential for exposure within the Rohm and Haas Company and the very low probability that this substance is in commerce elsewhere, Rohm and Haas Company does not believe that this exploratory chemical poses any substantial risk to health or the environment.

Rohm and Haas Company considers the exact identity of this chemical and its Rohm and Haas experimental designation number to be Confidential Business Information (CBI), and thus have enclosed with this letter a sanitized version for the public record with the confidential information deleted. We have also included, as Attachment II, substantiation supporting our CBI claims as required.

Rohm and Haas Company proposes the name "substituted benzamine" as a generic, non-confidential, chemical name to describe the chemical substance discussed in this notice.

If you have any questions concerning this submittal, my telephone number is (215) 592-2986.

Sincerely,

Senior Regulatory Specialist Product Integrity Department

GJP:cdg Enclosures

ATTACHMENT I



Generic name: Substituted benzamine

TRIAGE of 8(e) Submissions

| Date sent to triage: | | NON-CAP | CAP |
|---|------------|-----------------|-------|
| Submission number: 13 | 889 A | TSCA Inventory: | Y N D |
| STUDY TYPE (circle appr | opriate): | | |
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| Gordon Cash (E425) ECO AQU | ATO | | |
| Katherine Anitole (E613B) RTOX/DTOX |) | | |
| Daljit Sawhney (E611A) CTOX STO | X | • | |
| Deborah Norris (E606) NEUR | | ٠ | |
| Elizabeth Margosches (E6 EPI | 13C) | | |
| Michael Cimino (E611D) GTOX | | | |
| Leonard Keifer (E611C) Metabolism/Pharma | cokinetics | | |
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"13889A"="\"\"="ABSTRACT BASED ON SUMMARIZED RESULTS OF A STUDY IN PROGRESS SUBMITTED WITHOUT A REPORT. DIETARY CONCENTRATIONS OF 1000, 5000, AND 20000 PPM OF SUBSTITUTED BENZAMINE (CAS# CONFIDENT) WERE FED TO UN-NAMED ANIMALS AS PART OF AN ONGOING, 2-GENERATION REPRODUCTIVE STUDY. THERE WERE NO TREATMENT-RELATED EFFECTS ON BODY WEIGHTS OF PARENTAL ANIMALS, MATING OR FERTILITY PARAMETERS, NUMBERS AND SURVIVAL OF OFFSPRING, OR GROWTH OF OFFSPRING THROUGH DAY 14 OF LACTATION. TREATMENT-RELATED DECREASES IN PUP WEIGHT AND SPLEEN WEIGHT (BOTH ABSOLUTE AND RELATIVE TO BODY WEIGHT) AT DAY 21 OF LACTATION WERE OBSERVED AT ALL DOSES."